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10/563,828

05/08/2006

Per Wollmer

613-101

1945

23117 7590 09/28/2010
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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/563,828 | Applicant(s) WOLLMER ET AL. | |
| | Examiner JAGADISHWAR R. SAMALA | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Arguments and Remarks filed on 07/09/2010.

- Claims 19-27 are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection **is maintained** for reasons of record in the previous office action filed on 01/15/2010.

Applicant's arguments filed on 07/09/2010 have been fully considered but they are not persuasive.

Applicant argues that inventor Landh's and Wollmer declaration therein states that "the microemulsions of the present invention are reversed phase microemulsion of the type recited in the claims. This argument is not persuasive since the statement made by declaration can not be a supportive evidence of the originally filed

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specification. No where in specification it is mentioned that instant microemulsions are reversed phase microemulsions. The declaration states that it is necessary to have at least around 20% glycerol monooleate to form reversed phase microemulsion, but does not mention that instant invention (specification as filed) is a reversed phase microemulsion. Further, a general statement that the microemulsions of the current invention are reversed-phase, because they could not be anything other than reversed phase, this statement does not mean that the instant invention is related to reversed-phase microemulsions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linn et al (4,797,273) in view Rudnic et al (US 5,897,876) and Cho et al (US 5,665,700) **are maintained** for reasons of record in the previous office action filed on 01/15/2010.

Applicant's arguments filed on 07/09/2010 have been fully considered but they are not persuasive.

Applicant argues that there is no suggestion in Linn reference that the microemeulsions could be formed without the major polysiloxane or skin humectants components and nothing to suggest a monoacylglycerol, a non-polar vegetable oil and a surfactant could be used in combination without the other key components.

This argument is not persuasive since claim recites microemulsion comprising language and therefore does not exclude the presence of polysiloxane and humectants. The Linn does teach water-in-oil microemulsion composition comprising from about 3.0% to about 35% weight of vegetable oil, from about 20.0% to about 80.0% of microemulsion forming surfactant reads on alcohol (abstract and col. 4 lines 35-40). Applicant argues that Linn discloses various vegetable oils, but does not teach that these must be non-polar. This argument is not persuasive since Linn teaches various non-polar vegetable oils such as sesame oil (col.5 line 50), as recited in the instant claim 22. The same compound should have same property and obviously sesame oil will be non-polar. Applicant argues that a very long list of surfactants is disclosed by Linn. However, there is no teaching that these are particularly advantageous or any incentive for their selection from the list. This argument is not persuasive since whether among the short list or long list, Linn is suggestive of the claimed surfactants for

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microemulsions and therefore, one of ordinary skill in the art would be motivated to use these surfactants with a reasonable expectation of success.

Applicant argues that in Linn's reference there is no disclosure of the incorporation of a monoacyl glycerol. In response to applicant's argument against the reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.1086). In this case, the Linn reference is relied upon to show that it is known in the art to water-in-oil microemulsions comprising vegetable oil, surfactant, as well as polyhydric alcohols such as propylene glycol, glycerin or sorbitol to provide superior results when applied to skin following their application and Rudnic reference shows an equivalence that is recognized in the art for water-in-oil microemulsion comprising long chain fatty acid or esters such as glyceryl monooleate.

Applicant argues that Rudnic does not disclose the incorporation of 20-50 wt% monoacyl glycerol. This argument is not persuasive since Rudnic teaches in one embodiment the microemulsions comprising acetylated monoglycerides in amount of 10% (col. 9 lines 20-25). Furthermore, the optimization of the pharmaceutical formulation with ingredients well known in the pharmaceutical art is considered well within the competence level of an ordinary skilled artisan in the pharmaceutical sciences, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Applicant argues that Rudnic and Cho reference relates to oral administration and fails to disclose or teach the necessary modifications to the microemulsions of Linn et al. This argument is not persuasive since these references are combined for its teachings of knowledge in the art of employing mono-acyl glycerides such as glyceryl monooleate into microemulsions and this function would remain the same irrespective of whether the microemulsions were topically administered or orally administered.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618